

1 Boards and Commissions

2 Kentucky Board of Pharmacy

3 (Amended After Comments)

4 201 KAR 2:050. Licenses and permits; fees.

5 RELATES TO: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.0351(1), 315.036(1),

6 315.050(5), 315.060, 315.110, 315.120, 315.191, 315.402

7 STATUTORY AUTHORITY: KRS 218A.205(3)(g), 315.035(1), (2), (4), 315.036(1),

8 315.050(5), 315.060, 315.110(1), 315.120(4), 315.191(1)(i), 315.402(1)

9 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(i) authorizes the

10 board to assess reasonable fees for services rendered to perform its duties and respon-

11 sibilities. This administrative regulation establishes reasonable fees for the board to per-

12 form all the functions for which it is responsible.

13 Section 1. The following fees shall be paid in connection with pharmacist examinations

14 and licenses, pharmacy permits, intern certificates, and the issuance and renewal of li-

15 censes and permits:

16 (1) Application for initial pharmacist license – \$150;

17 (2) Application and initial license for a pharmacist license by license transfer - \$250;

18 (3) Annual renewal of a pharmacist license – ninety-five (95) dollars;

19 (4) Delinquent renewal penalty for a pharmacist license – ninety-five (95) dollars;

20 (5) Annual renewal of an inactive pharmacist license—ten (10) dollars;

21 (6) Pharmacy intern certificate valid six (6) years –twenty-five (25) dollars;

- 1 (7) Duplicate of original pharmacist license wall certificate - seventy-five (75) dollars;
- 2 (8) Application for a permit to operate a pharmacy - \$150 [~~\$125~~];
- 3 (9) Renewal of a permit to operate a pharmacy - \$150 [~~\$125~~];
- 4 (10) Delinquent renewal penalty for a permit to operate a pharmacy – \$150 [~~\$100~~] dollars;
- 5 (11) Change of location or change of ownership of a pharmacy or manufacturer permit -
- 6 \$150 [~~seventy-five (75) dollars~~];
- 7 (12) Application for a permit to operate as a manufacturer - \$150 [~~\$125~~];
- 8 (13) Renewal of a permit to operate as a manufacturer - \$150 [~~\$125~~];
- 9 (14) Delinquent renewal penalty for a permit to operate as a manufacturer - \$150 [~~\$125~~];
- 10 (15) Change of location or change of ownership of a wholesale distributor license - \$150
- 11 [~~seventy-five (75) dollars~~];
- 12 (16) Application for a license to operate as a wholesale distributor -\$150 [~~\$125~~];
- 13 (17) Renewal of a license to operate as a wholesale distributor -\$150 [~~\$125~~];
- 14 (18) Delinquent renewal penalty for a license to operate as a wholesale distributor -\$150
- 15 [~~\$125~~]; and
- 16 (19) Query to the National Practitioner Data Bank of the United States Department of
- 17 Health and Human Services – twenty-five (25) dollars;:-

18 Section 2. Incorporation by Reference. (1) The following material is incorporated by ref-

19 erence:

- 20 (a) “Application for Non-Resident Pharmacy Permit, Form 3, 9/2023 [6/2023]
- 21 (b) Application for Non-Resident Pharmacy Permit Renewal, Form 4, 9/2023 [6/2023]
- 22 (c) Application for Permit to Operate a Pharmacy in Kentucky, Form 1, 6/2023
- 23 (d) Application for Resident Pharmacy Permit Renewal, Form 2, 6/2023
- 24 (2) This material may be inspected, copied, or obtained subject to applicable copyright

- 1 law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125
- 2 Holmes Street, Frankfort, Kentucky, 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
- 3 This material is also available on the board's website at [https://pharmacy.ky.gov/Busi-](https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx)
- 4 [nesses/Pages/Pharmacy.aspx.](https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx)



Christopher Harlow, Pharm.D.
Executive Director
Board of Pharmacy

September 11, 2023

STATEMENT OF CONSIDERATION
Relating to 201 KAR 2:050

BOARDS AND COMMISSIONS, Kentucky Board of Pharmacy
(Amended After Comments)

- I. The public hearing on 201 KAR 2:050 scheduled for August 30th via zoom tele-conference was canceled; however, a written comment was received during the public comment period.

- II. The following person submitted written comment:

<u>Name and Title</u>	<u>Agency/Organization/Entity/Other</u>
Kristine Burrows, Chief Operating Officer	State Licensing Servicing, Inc.

- III. The following people from the promulgating administrative body attended the public hearing and responded to the comments:

Name and Title
Dr. Christopher Harlow, Executive Director, Kentucky Board of Pharmacy
John Fuller, President, Kentucky Board of Pharmacy
Jonathan Van Lahr, Vice-President, Kentucky Board of Pharmacy
Peter Cohron, Kentucky Board of Pharmacy
Meredith Figg, Kentucky Board of Pharmacy
Anthony Tagavi, Kentucky Board of Pharmacy
Jason Belcher, Kentucky Board of Pharmacy
Eden Davis, General Counsel, Kentucky Board of Pharmacy

- IV. Summary of Comments and Responses

1. Subject Matter: Non-Resident Application Registration Status
 - (a) Comment: Kristine Burrows – State Licensing Servicing, Inc. requested that an not applicable box be added to the non-resident application seeing that KRS .0-010 explicitly exempts interstate commerce in the definition of transacting business.
 - (b) Response: The Board agrees that KRS .0-010 does exempt interstate commerce from the definition of transacting business and therefore the

Board agrees to add the not applicable box to the non-resident application.

V. Summary of Statement of Consideration and Action Taken by Promulgating Administrative Body

The public hearing on this administrative regulation was canceled; however, a written comment was received. The Board of Pharmacy responded to the comment and amends the administrative regulation as follows:

Page 2

Section 2

Line 20

After Form 3, insert the following: **9/2023**

Delete "6/2023".

Page 2

Section 2

Line 21

After Form 4, insert the following: **9/2023**

Delete "6/2023".

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:050 Licenses and Permits; fees.

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

1. Provide a brief summary of:

a. What this administrative regulation does: This administrative regulation establishes the fees associated with Board of Pharmacy licensure.

b. The necessity of this administrative regulation: KRS 315.191(1)(i) authorizes the Board of Pharmacy to assess reasonable fees for services rendered to perform its duties and responsibilities. This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is responsible.

c. How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes reasonable fees for the board to perform all the functions for which it is reasonable.

d. How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation allows for the funding to support Board administration.

2. If this is an amendment to an existing administrative regulation, provide a brief summary of:

a. How the amendment will change this existing administrative regulation: The amendment increases fees for facilities permitted by the Board.

b. The necessity of the amendment to this administrative regulation: This administrative regulation is necessary to ensure the Board is appropriately funded to cover personnel costs and comply with the administrative functions required for pharmacies, wholesale distributors, and manufacturers.

c. How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(i) authorizes the Board of Pharmacy to assess reasonable fees for services rendered to perform its duties and responsibilities.

d. How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of permitted entities.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacists will be affected minimally by this regulation amendment. Pharmacies, manufacturers and wholesale distributors will have increased fees of twenty-five dollars (25) for a new or a renewal license or permit. The application for change in location or change in ownership will have the same fee as the new and renewal applications because they require completion of a new application.

4. Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

a. List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: During renewal, the identified entities will have an increased permitting fee to pay.

b. In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Cost of compliance for pharmacies, wholesale distributors, and manufacturers will be \$150.

c. As a result of compliance, what benefits will accrue to the entities identified in question (3): These entities will have the benefit of ensured compliance with federal law due to the state adoption of the federal licensing standards.

5. Provide an estimate of how much it will cost to implement this administrative Regulation:

a. Initially: No costs will be incurred.

b. On a continuing basis: No costs will be incurred.

Other explanation: n/a

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from fees provide the funding to enforce the regulation.

7. Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: Yes, this regulation assesses an increase in fees. The increase in fees are necessary to properly fund the Board for the administrative activities related to licensing and inspection to ensure the Board is achieving its mission of public and patient safety.

8. State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: Yes, fees for pharmacies, manufacturers, and wholesale distributors.

9. TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not

applied because the regulation is applicable to all pharmacies, wholesale distributors, and manufacturers.

FISCAL NOTE

Regulation No. 201 KAR 2:050 Licenses and Permits; fees.

Contact Person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

1. What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be the only entity impacted by this administrative regulation.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(i); 315.035(4); 315.036(1); 315.110(1).

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The proposed amendment will increase revenue by \$91,925.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The proposed amendment will increase revenue by \$91,925.

(c) How much will it cost to administer this program for the first year? The Board of Pharmacy does not anticipate any additional cost to administer this regulation for the first year.

(d) How much will it cost to administer this program for subsequent years? The Board of Pharmacy does not anticipate any additional cost to administer this regulation for the first year.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): Amendment will provide an annual \$91,925 in revenue.

Expenditures (+/-): 0

Other Explanation: n/a

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? None.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? None.

(c) How much will it cost the regulated entities for the first year? \$150 per permit.

(d) How much will it cost the regulated entities for subsequent years? \$150 annually.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-): 0

Expenditures (+/-): -\$150

Other Explanation: n/a

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.

Summary of Material Incorporated by Reference

The “Application for “Non-Resident Pharmacy Permit”, September 2023 form is the 19-page form to be utilized by applicants for an initial non-resident pharmacy permit.

The “Application for “Non-Resident Pharmacy Permit –Renewal”, September 2023 is the 16-page form to be utilized by applicants for annual non-resident pharmacy permit renewal.

The “Application to Operate a Pharmacy in Kentucky”, June 2023 form is the 11-page form to be utilized by applicants for an initial resident pharmacy permit.

The “Application for “Resident Pharmacy Permit –Renewal”, June 2023 form is the 12-page form to be utilized by applicants for annual resident pharmacy permit renewal.

Summary of Changes to Material Incorporated by Reference

The “Application for “Non-Resident Pharmacy Permit”, June 2023 form was amended to add a box under section III to include “not applicable” for those non-resident pharmacies not registered with the Kentucky Secretary of State. The edition therefore changed to September 2023.

The “Application for “Non-Resident Pharmacy Permit—Renewal”, June 2023 form was amended to add a box under section III to include “not applicable” for those non-resident pharmacies not registered with the Kentucky Secretary of State. The edition therefore changed to September 2023.

Final, 10-02-2023

STAFF-SUGGESTED AMENDMENT

**BOARDS AND COMMISSIONS
Kentucky Board of Pharmacy**

(Amended After Comments Version)

201 KAR 2:050. Licenses and permits; fees.

Page 2

Section 1(19)

Line 17

After "(25) dollars", insert a period.
Delete the semicolon.

Page 2

Section 2

Line 18

After "Section 2.", insert the following:

An applicant shall submit:

(1) An initial or renewal application for a pharmacy permit on either the:

(a) 1. Application for Permit to Operate a Pharmacy in Kentucky; or

2. Application for Resident Pharmacy Permit Renewal; or

(b) 1. Application for Non-Resident Pharmacy Permit; or

2. Application for Non-Resident Pharmacy Permit Renewal; and

(2) As appropriate, the:

(a) Initial application fee established by Section 1(8) of this administrative regulation; or

(b) Renewal fee established by Section 1(9) of this administrative regulation.
Section 3.

Page 2

Section 2(1)(a) (Renumbered as Section 3(1)(a))

Line 20

After "Permit", insert closing quotation marks.

Page 2

Section 2(1)(b) (Renumbered as Section 3(1)(b))

Line 21

After "(b)", insert opening quotation marks.

After "Renewal", insert closing quotation marks.

Page 2

Section 2(1)(c) (Renumbered as Section 3(1)(c))

Line 22

After "(c)", insert opening quotation marks.

After "Kentucky", insert closing quotation marks.

Page 2
Section 2(1)(d) (Renumbered as Section 3(1)(d))
Line 23

After “(d)”, insert opening quotation marks.
After “Renewal”, insert closing quotation marks.

Page 2
Section 2(2) (Renumbered as Section 3(2))
Line 24

After “obtained”, insert a comma.

MATERIAL INCORPORATED BY REFERENCE

At the time that it files this staff suggested amendment, the agency needs to file one (1) clean copy of each of the following:

- **The “Application for Non-Resident Pharmacy Permit”, Form 3 that was missing from its 6/7 filing that has the 6/2023 edition date**
- **The “Application for Non-Resident Pharmacy Permit Renewal”, Form 4 that was missing from its 6/7 filing that has the 6/2023 edition date**